

Remarks

1. In the Office Action of June 20, 2002, the Examiner considered Claims 25-41 to be subject to restriction requirement. Specifically, the Examiner required the Applicants to elect among the following groups:
  - I. Claims 25-26, 32-36 drawn to a pharmaceutical compound comprising an amino acid sequence of SEQ ID NO: 1, classified in class 530, subclass 326, for example.
  - II. Claims 25, 27, 32-36 drawn to a pharmaceutical compound comprising an amino acid sequence of SEQ ID NO: 2, classified in class 530, subclass 326, for example.
  - III. Claims 25, 28, 32-36 drawn to a pharmaceutical compound comprising an amino acid sequence of SEQ ID NO: 3, classified in class 530, subclass 326, for example.
  - IV. Claims 25, 29, 32-36 drawn to a pharmaceutical compound comprising an amino acid sequence of SEQ ID NO: 4, classified in class 530, subclass 326, for example.
  - V. Claims 25, 30 , 32-36 drawn to a pharmaceutical compound comprising an amino acid sequence of SEQ ID NO: 5, classified in class 530, subclass 326, for example.
  - VI. Claims 25, 31-36 drawn to a pharmaceutical compound comprising an amino acid sequence of SEQ ID NO: 7, classified in class 530, subclass 326, for example.
  - VII. Claim 37 drawn to a method of treating a disease by administering a pharmaceutical compound comprising amino acid sequence of SEQ ID NO: 1, classified in class 514, subclass 2, for example.
  - VIII. Claim 37 drawn to a method of treating a disease by administering a pharmaceutical compound comprising amino acid sequence of SEQ ID NO: 2, classified in class 514, subclass 2, for example.

- IX. Claim 37 drawn to a method of treating a disease by administering a pharmaceutical compound comprising amino acid sequence of SEQ ID NO: 3, classified in class 514, subclass 2, for example.
- X. Claim 37 drawn to a method of treating a disease by administering a pharmaceutical compound comprising amino acid sequence of SEQ ID NO: 4, classified in class 514, subclass 2, for example.
- XI. Claim 37 drawn to a method of treating a disease by administering a pharmaceutical compound comprising amino acid sequence of SEQ ID NO: 5, classified in class 514, subclass 2, for example.
- XII. Claim 37 drawn to a method of treating a disease by administering a pharmaceutical compound comprising amino acid sequence of SEQ ID NO: 7, classified in class 514, subclass 2, for example.
- XIII. Claims 38-41, drawn to nucleic acid molecule encoding a polypeptide of SEQ ID NO: 1, vector and a host cell, classified in class 435, subclass 69.1., for example.
- XIV. Claims 38-41, drawn to nucleic acid molecule encoding a polypeptide of SEQ ID NO: 2, vector and a host cell, classified in class 435, subclass 69.1., for example.
- XV. Claims 38-41, drawn to nucleic acid molecule encoding a polypeptide of SEQ ID NO: 3, vector and a host cell, classified in class 435, subclass 69.1., for example.
- XVI. Claims 38-41, drawn to nucleic acid molecule encoding a polypeptide of SEQ ID NO: 4, vector and a host cell, classified in class 435, subclass 69.1., for example.
- XVII. Claims 38-41, drawn to nucleic acid molecule encoding a polypeptide of SEQ ID NO: 5, vector and a host cell, classified in class 435, subclass 69.1., for example.
- XVIII. Claims 38-41, drawn to nucleic acid molecule encoding a polypeptide of SEQ ID NO: 7, vector and a host cell, classified in class 435, subclass 69.1., for example.

XIX. Claims 38-41, drawn to nucleic acid molecule encoding a polypeptide of SEQ ID NO: 8, vector and a host cell, classified in class 435, subclass 69.1., for example.

In order to more particularly point out and distinctly claim their invention, Applicants have cancelled Claims 25-41 herein and present new claims 42-58 pursuant to MPEP Section 800. Specifically, the new claims clearly point out that applicants' invention features an amino acid motif of the formula  $Y_1-X_1-X_2-Y_2-Y_3-Y_4-X_3-X_4-X_5-Y_5-X_6-X_7-X_8-X_9-X_{10}-Y_6$  and clearly set forth the metes and bounds of the formula which is common to the sequences from which the compounds of the invention are derived. In light of the cancellation of claims 25-41, Applicants respectfully request reconsideration of the Restriction Requirement pursuant to MPEP Section 800.

Regarding the Examiner's action, applicants respectfully point out that independent claims 25, 32, 33, 37 and 38, which were subject to restriction, were not limited by applicants to pharmaceutical compounds comprising amino acid sequences of SEQ NO. 1, SEQ NO. 2, SEQ NO. 3, SEQ NO. 4, SEQ NO. 5 OR SEQ NO 7 as suggested by the Examiner in the Office Action under reply. Rather, the independent claims were directed to pharmaceutical compounds, methods of using the compounds and related nucleic acids, which have a common generic amino acid motif. The generic polypeptide motif which applicants identified as SEQ. ID 8 in independent claim 25, for example, is common to SEQ. IDs 1,2,3,4,5, and 7 as set forth in dependent claims 26-31. Thus, the subject matter of independent claim 25 encompasses the subject matters of dependent claims 26-31. Likewise, independent claims 32 , 33, 37 and 38, encompass, but are not limited to, pharmaceutical

compounds comprising amino acid sequences of SEQ NO 1, SEQ NO 2, SEQ NO 3, SEQ NO 4, SEQ NO 5, SEQ NO 7.

Applicants respectfully submit that they, not the Patent Office, must define the invention and set forth the metes and bounds of such invention. If this were not the case, then the invention so prescribed may not meet the description requirement of 35 U.S.C. §112. See *In re Wolfrum and Gold* at 622. Applicants have the right to claim their invention using the limitations that they regard as essential to delineate the invention, as long as the requirements of 35 U.S.C. §112 are met. As stated above Applicants have cancelled Claims 25-41 herein and present new claims 42-58 which more particularly point out and distinctly claim their invention. Applicants have corrected the claim language in the new claims presented herein, such that the amino acid motif is defined by its formula and is no longer identified as "SEQUENCE ID NO. 8".

The CCPA states in *Wolfrum et al., supra*, that under the provisions of 35 U.S.C. §112,

"the scope of the subject matter is governed not by the examiner's conception of the 'invention' but by that "which the applicant regards as his invention"....Applicant is free under that provision to set the metes and bounds of 'his invention' as he sees them."

In order to comply with the outstanding the outstanding Restriction Requirement Applicants elect, with traverse, Group I comprising claims 25-26, 32-36 for further examination. Applicants again point out, however, that independent claim 25 encompasses,

but is not limited to, to pharmaceutical compounds comprising an amino acid sequences of SEQ NO 1, SEQ NO 2, SEQ NO 3, SEQ NO 4, SEQ NO 5 or SEQ NO 7.

2. In the Office Action under reply, the Examiner stated that Groups I -VI are unrelated because they are directed to compounds that have different chemical structures and are not required for one another. Applicants respectfully disagree and traverse based on the Examiner's mischaracterization of independent claim 25 as noted above. As set forth by Applicants, independent Claim 25 is directed to a generic sequence motif that encompasses all of the sequences of claims 26-36. Whether the claimed species are patentably distinct is irrelevant to the determination of patentability of applicants' claims directed to the species and the generic claims that read on these species. In view of the presence of a generic claim in the present invention, each and every species falling with that generic claim should be examined on the merits.

3. In the Office Action under reply, the Examiner stated that while the inventions of Groups I- VI and XIII-XIX are related as product and process of use, they are distinct and independent. Applicants respectfully traverse the restriction. There are two criteria for a proper restriction requirement: the application contains independent or distinct inventions, and there is a serious burden on the Patent Office to exam the application without an election. MPEP § 803. Here, the subject matters of the above listed groups are related to each other. A search of the subject matter in one group would often reveal references to the subject matters of other groups. Therefore, it would be convenient and productive, not burdensome,

to search and examine all the subject matters in groups I-VI and XIII-XIX in one single application.

4. In the Office Action under reply, the Examiner states that the inventions of Groups VII-XII and XIII-XIX are unrelated because "the DNA groups of XIII-XIX are not required for the methods of groups VII-XII." Applicants respectfully disagree and traverse on the grounds that the examiner has not shown there is a serious burden on the Patent Office to exam the application without an election. Here, the subject matters of the above listed groups are related to each other. A search of the subject matter in one group would often reveal references to the subject matters of other groups. Therefore, it would be convenient and productive, not burdensome, to search and examine all the subject matters in groups VII-XII and XIII-XIX in one single application.

5. In the Office Action under reply, the Examiner stated that Groups XIII-XIX are unrelated because they are directed to compounds that have different chemical structures and are not required for one another. Applicants respectfully disagree and traverse based on the Examiner's mischaracterization of independent claims 25 and 38 as noted above. As set forth by Applicants, independent Claim 25 is directed to a generic sequence motif that encompasses all of the sequences. The common generic motif encompasses SEQ. IDs 1,2,3,4,5, and 7. It is immaterial that the generic motif covers a plurality of independent and distinct patentable inventions. That is the purpose of a generic claim.

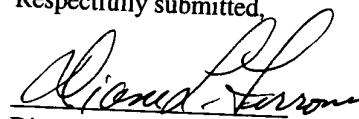
6. In the Office Action under reply, the Examiner stated that Groups VII-XIII-are unrelated because they are directed to compounds that have different chemical structures and are not required for one another. Applicants respectfully disagree and traverse based on the Examiner's mischaracterization of independent claims 25 and 37 as noted above. The common generic motif encompasses SEQ. IDs 1,2,3,4,5, and 7. It is immaterial that the generic motif covers a plurality of independent and distinct patentable inventions. That is the purpose of a generic claim.

7. Applicants respectfully submit that they are entitled to a complete action on the merits of all claims, including all species encompassed by the claims. New independent claim 42 contains the subject matter of cancelled claim 25 and all species encompassed thereby including but not limited to the species set forth in new dependent claim 43 which contains the subject matter of cancelled claims 26-31. Likewise, the remainder of the independent claims presented herein encompass the subject matter of their corresponding dependent claims. Without the showing of undue burden, it is improper to impose a restriction requirement on the application. The mere fact that the subject matters of the groups belong to different classes or subclasses is only a *prima facie* showing of a serious burden of examination. *Id.* As stated above, the inventions identified are sufficiently related to one another that it would be convenient and productive, not burdensome, to search and examine all the subject matters in one single application.

Applicants look forward to having all claims considered on the merits. If a telephone interview would assist in advancing the prosecution of the subject application, the Examiner is invited to telephone applicant's undersigned attorney at the number provided.

No fees are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge **Deposit Account No. 03-3839** for any underpayment, or to credit any overpayments.

Respectfully submitted,

 7/22/02  
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